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EXAMINER

SWOPE, SHERIDAN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/655,345

Applicant(s)

MCDANIEL, C. STEVEN

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-256 and 269-321 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10, 64, 67, 68, 72-76, 79-83, 88, 89, 94-97, 103, 105, 109-112, 126-131, 180-182, 217, 251, 252, 269-271, 275-278, 282-285, 289-292, 296, 312, 319, and 320 is/are rejected.
- 7) ☒ Claim(s) 9, 181, 182, 252, 275, 289 and 320 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1104; 1204</u> . | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 7, 11-63, 65, 66, 69-71, 77, 78, 84-87, 90-93, 98-102, 104, 106-108, 113-125, 132-179, 183-216, 218-250, 253-256, 272-274, 279-281, 286-288, 293-295, 297-311, 313-318 and 321.

Continuation of Attachment(s) 6). Other: front page from defective reference.

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DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

Applicant's election, without traverse, of Invention I, Claims 1-256, as well as enzyme, paint, water, and ambient conditions in their response of October 17, 2005 is acknowledged. It is pointed out that the original restriction group (A) "enzyme", of June 20, 2005, is a distinct invention that encompasses those enzymes not listed in groups (G)-(QQQ). It is further acknowledged that Claims 269-321 fall within the original Invention I, as set forth in the Restriction Requirement of June 20, 2005. Claims 1-256 and 269-321 are pending. Claims 7, 11-63, 65, 66, 69-71, 77, 78, 84-87, 90-93, 98-102, 104 106-108, 113-125, 132-179, 183-216, 218-250, 253-256, 272-274, 279-281, 286-288, 293-295, 297-311, 313-318, and 321 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1-6, 8-10, 64, 67, 68, 72-76, 79-83, 88, 89, 94-97, 103, 105, 109-112, 126-131, 180-182, 217, 251, 252, 269-271, 275-278, 282-285, 289-292, 296, 312, 319, and 320 are hereby examined.

Priority

The priority date granted for the instant invention is September 9, 2002, the filing date of provisional application US60/409,102.

Title

The title is objected to because it is not descriptive of the elected invention.

Abstract

The abstract is objected to because it fails to describe the complete subject matter of the disclosure.

MPEP 608.01(b) states

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

Specification-Objections

The specification is objected to for containing hyperlinks. USPTO policy does not permit the USPTO, i.e, via an issued patent, to link to any commercial sites, since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. Hyperlinks and other forms of browser-executable code, especially commercial site URLs, are not to be included in a patent application. (MPEP 608.01) The specification, including the IDS, should be carefully checked and all URLs removed.

Information Disclosure Statement (IDS)

37 CFR 1.98(b) requires that each item of information in an IDS be identified properly. Each publication must be identified by publisher, author (if any), title, relevant pages of the publication, and date and place of publication. The date of publication supplied must include at least the month and year of publication, except that the year of publication (without the month) will be accepted if the applicant points out in the information disclosure statement that the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue.

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The IDS of December 16, 2004 is objected to because all of the nonpatent references are incomplete or improper. The IDS of November 23, 2004 is objected to because the following nonpatent references are incomplete or improper.

Page 1, references 3-6 and 8

Page 2, references 9, 10, and 13

Page 3, reference 7.

Page 4, references 7, 13, and 14.

Page 5, references 7-17.

Page 6, references 1-4.

The IDS of November 23, 2004 is also objected to because the listing for published US patents and patent applications fails to state the inventor's name.

An IDS containing the corrected citations listed above is required.

References

One of the references submitted by Applicants is completely illegible (see enclosure). Applicants are required to submit a new copy that is legible and include, if appropriate, the citation on the new IDS, as required above.

Claims-Objections

Claims 9, 181, 182, and 320 are objected to for reciting non-elected subject matter.

Claim 252 is objected to for the phrase "a two to five containers", which should be "two to five containers".

Claims 275 and 289 are objected to for the phrase "material that comprises", which should be "material comprises".

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Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 1-6, 8-10, 64, 67, 68, 72-76, 79-83, 88, 89, 94-97, 103, 105, 109-112, 126-131, 180-182, 217, 251, 252, 269-271, 275-278, 282-285, 289-292, 296, 312, 319, and 320 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-8 and 185-195 of US Application 10/855,344. Although the conflicting claims are not identical, they are not patentably distinct from each other. The elected claims herein and Claims 1-8 and 185-195 of 10/855,344 are both directed to coatings comprising biomolecules. The claims differ in that the claims of the invention elected herein

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recite some specific limitation for said coatings, i.e., thickness and viscosity, while Claims 1-8 and 185-195 of 10/855,344 recite some coatings comprising specific biomolecules, as disclosed by their amino acid sequences. The portion of the specification in 10/855,344 that supports the recited coatings includes embodiments that would anticipate the elected claims herein, e.g., coatings comprising biomolecules, which are also the products specifically recited in Claims 1-8 and 185-195 of 10/855,344. Claims 1-6, 8-10, 64, 67, 68, 72-76, 79-83, 88, 89, 94-97, 103, 105, 109-112, 126-131, 180-182, 217, 251, 252, 269-271, 275-278, 282-285, 289-292, 296, 312, 319, and 320 herein cannot be considered patentably distinct over Claims 1-8 and 185-195 of 10/855,344 when there are specifically recited embodiments (coatings comprising biomolecules) that would anticipate said claims herein. Alternatively, said claims herein cannot be considered patentably distinct over Claims 1-8 and 185-195 of 10/855,344 when there are specifically disclosed embodiments in 10/855,344 that supports Claims 1-8 and 185-195 of that patent and falls within the scope of the elected claim herein, because it would have been obvious to a skilled artisan to modify the products of Claims 1-8 and 185-195 of 10/855,344 by selecting a specifically disclosed embodiments that supports those claims, i.e., coatings comprising biomolecules, as disclosed in 10/855,344. One having ordinary skill in the art would have been motivated to do this, because such an embodiment, is disclosed as being a preferred embodiment within Claims 1-8 and 185-195 of 10/855,344.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8-10, 64, 67, 68, 72-76, 79-83, 88, 89, 94-97, 103, 105, 109-112, 126-131, 180-182, 217, 251, 252, 269, 275-278, 282-285, 289-292, 296, 312, 319, and 320 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

The phrase “active biomolecule” in Claims 1, 269, 275-277, 282, 283, 289-291, 296, 312, and 319 renders the claims indefinite. The specification states:

‘Specific examples of such activity by a biomolecule include an antibody binding an antigen, a cell receptor binding a ligand, an enzyme binding a substrate, a transport protein may bind a ligand, etc. In some aspects, binding a ligand may be a desired activity such as, for example, to sequester an undesired molecule, such as a toxin, to the biomolecule. Often, a biomolecule’s activity further comprises a specific chemical reaction in addition to a physical/chemical affinity for another molecule. For example, an enzyme may accelerate a chemical reaction upon the bound substrate, a cell receptor may change conformation and/or become enzymatically active or inactive toward a second substrate, a transport protein may mitigate the movement of a molecule, etc. In another example, a biomolecule may comprise a ligand that induces or inhibits such activity in an enzyme, a cell receptor, a transport protein, and the like.

An “active biomolecule” refers to biomolecule that retains these types of properties in a coating of the present invention. The ability to confer bioactivity to a coating provides numerous uses in addition to the preferred bioactivity of detoxification of OP compounds.’

Said definition for “active biomolecule” is indefinite because it is only exemplary.

Furthermore, not all biomolecules would have all said exemplary activities and neither the specification nor the claims clearly define the activity of any specific biomolecule recited by Claims 1, 269, 275-277, 282, 283, 289-291, 296, 312, and 319. Claims 2-6, 8-10, 64, 67, 68, 72-

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76, 79-83, 88, 89, 94-97, 103, 105, 109-112, 126-131, 180-182, 217, 251, 252, as being dependent from Claim 1, and Claim 320, as dependent from Claim 319, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the same reasons.

In Claim 5, the phrase “the ligand comprises an antigen, ... or a combination thereof” renders the claim indefinite. A ligand cannot have all of the characteristics listed.

In Claim 8, the phrase “the proteinaceous molecule comprises a peptide, a polypeptide, a protein or a combination thereof” renders the claim indefinite. A proteinaceous molecule is all of the recited, but “a combination thereof” is confusing.

In Claim 9, the phrase “the proteinaceous molecule comprises an enzyme, ... or a combination thereof” renders the claim confusing, as a person of ordinary skill in the art would believe that more likely than not, one proteinaceous molecule cannot have all of the characteristics listed.

For Claim 64 the phrase “contacts a living organism” is confusing. It is unclear what “contact” means; do Applicants mean “binds to a living organism”? Said phrase is further indefinite because it is unclear whether the “contacting” or binding occurs while the proteinaceous molecule is a component of the coating.

Claim 74, 75, 83 are indefinite for not defining whether the thickness of the coating is when the coating is wet, dry, or both wet and dry.

The term “ambient conditions” in Claim 89 is a relative term that renders Claims 89 indefinite. The term is not defined by the claims, the specification does not provide a standard for ascertaining the requisite conditions, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

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For Claim 105, the phrase “a concentration that is insufficient to produce a solid” is a relative phrase that renders the claim indefinite. Neither the specification nor the claims provide a means to determine the concentration that is required, or that is insufficient, to form a solid; methods to measure whether the film is a solid or not are not disclosed. A person of ordinary skill in the art would not know the metes and bounds of the recited invention. Claim 109, as dependent from Claim 105 is indefinite for the same reasons.

Claim 110 is indefinite for being dependent on itself. For purposes of examination, it is assumed that Claim 110 is dependent from Claim 1. Claims 111 and 112, as dependent from Claim 110, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the same reasons.

The term “temporary” in Claims 110 and 111 is a relative term that renders said claims indefinite. The term is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Claim 112, as dependent from Claim 110, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the same reasons.

The term “poor” in Claim 112 is a relative term that renders said claims indefinite. The term is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Claims 73, 75, 252, 276, 278, 282-285, 289-292, and 320 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for having improper antecedent usage as follows.

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For Claim 73, “the buffer” has no antecedent basis.

For Claims 75 and 252, “the surface” has no antecedent basis.

For Claims 282-285 and 289-292, “the improvement” has no antecedent basis.

For Claims 276, 278, 290 and 292, “the particulate material” should be “the whole cell particulate material”.

For Claim 320, “A surface treatment of Claim 319” should be “The surface treatment of Claim 319”.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

In this regard, the application disclosure and claims are compared per the factors indicated in the decision *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

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Claims 1-6, 8-10, 64, 67, 68, 72-76, 79-83, 88, 89, 94-97, 103, 105, 109-112, 126-131, 180-182, 217, 251, 252, 269-271, 275-278, 282-285, 289-292, 296, 312, 319, and 320 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a paint comprising enzymatically active organophospho hydrolase, as disclosed in Examples 3-5, does not reasonably provide enablement for any coating, having any composition, and containing any active biomolecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1-6, 8, 64, 67, 68, 72-76, 79-83, 88, 89, 94-97, 103, 105, 109-112, 126-131, 180-182, 217, 251, 252, 269-270, 275-277, 282-284, 289-291, 296, 312, 319, and 320 are so broad as to encompass any coating, having any composition, and comprising any active biomolecule. Claim 9, 10, 271, 278, 285, and 292 are so broad as to encompass any coating, having any composition, and comprising any active enzyme. The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of coatings, having any composition, and comprising an extremely large number of active biomolecules or active enzymes, as broadly encompassed by the claims. Since the compositions of a coating determines whether a biomolecule will remain active in said coating, predictability of which biomolecules and enzymes can remain active in any coating requires a knowledge of how each component of a coating's composition affects the activity of any specific biomolecule. In addition, since the amino acid sequence of a protein determines its structural and functional properties, predictability of which biomolecules and enzymes can remain active in any coating requires a knowledge of and guidance with regard to the relationship of the structure

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of any active biomolecule to its function and whether the structure of any specific biomolecule will allow it to remain active in any coating. Furthermore, which amino acids in the protein's sequence, if any, are tolerant modification and which are conserved (i.e. expectedly intolerant to modification), and whether any amino acids in the protein's sequence can be altered to support activity in any coating also requires a detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the paint comprising enzymatically active organophospho hydrolase, as disclosed in Examples 3-5.

While methods for testing the activity of a biomolecule in any coating composition as well as recombinant and mutagenesis techniques to design proteins with desired traits are known, it is not routine in the art to screen the activity of multiple biomolecules with substitutions or multiple modifications in multiple coatings comprising an essentially unlimited number of possible components, as encompassed by the instant claims. Furthermore, formulation of a coating comprising a specific combination of components in order to successfully support the activity of any specific biomolecule's activity is unpredictable (Drevon et al, 2002; IDS). In addition, the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are also unpredictable (Galye et al, 1993; Whisstock et al, 2003). Moreover, one skilled in the art would expect any tolerance to modification for a given biomolecule to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of Claims 1-6, 8, 64, 67, 68, 72-76, 79-83, 88, 89, 94-97, 103, 105, 109-112, 126-131, 180-182, 217, 251, 252, 269-270, 275-277,

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282-284, 289-291, 296, 312, 319, and 320 which, encompasses all coatings comprising any active biomolecule. The specification does not support the broad scope of Claims 9, 10, 271, 278, 285, and 292, which encompasses any coating comprising any active enzyme. The specification does not support the broad scope of Claims 1-6, 8-10, 64, 67, 68, 72-76, 79-83, 88, 89, 94-97, 103, 105, 109-112, 126-131, 180-182, 217, 251, 252, 269-271, 275-278, 282-285, 289-292, 296, 312, 319, and 320 because the specification does not establish: (A) all biomolecules that are active in any coating; (B) regions of the protein structure which may be modified without effecting the activity of any biomolecule in any coating; (C) regions of the protein structure which may be modified support the activity of any biomolecule in any coating; (D) the general tolerance of the activity of any biomolecule to any coating; (E) the general tolerance of the activity of any biomolecule to modification and extent of such tolerance; (F) the composition of coatings that can be used to support the activity of all recited biomolecules; (G) components of any coating that can be changed to support the activity of any specific biomolecule; (G) components of any coating that must not be changed in order to support the activity of any specific biomolecule; (H) a rational and predictable scheme for choosing any biomolecule to be active in any coating; (I) a rational and predictable scheme for modifying any biomolecule with an expectation of obtaining the desired biological function; (J) a rational and predictable scheme for formulating any coating with an expectation of obtaining the desired ability to support the activity of any specific biomolecule; and (K) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

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Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of coatings, with any composition, and comprising any number of active biomolecules or active enzymes. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Written Description

Claims 1-6, 8-10, 64, 67, 68, 72-76, 79-83, 88, 89, 94-97, 103, 105, 109-112, 126-131, 180-182, 217, 251, 252, 269-271, 275-278, 282-285, 289-292, 296, 312, 319, and 320 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of coatings, with any components, and containing any active biomolecule or any active enzyme. The specification teaches only a single representative species of such coatings. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of being a coating, or any composition, and containing any active biomolecule or any active enzyme. Given this lack of description of representative species encompassed by the genus of

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the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8-10, 64, 67, 68, 72, 76, 88, 89, 94-97, 110, 126, 128, 180-182, 217, 269-271, 282-285, 296, 319, and 320 rejected under 35 U.S.C. 102(b) as being anticipated by Sau et al, 1999 (Example 9). Sau et al teach a coating that is an aqueous buffered paint comprising an enzyme at a concentration between 0.001-40%, wherein the paint has a viscosity between 75-95 Ku and forms a temporary film by the loss of a volatile diluent.

Claims 1-5, 8-10, 64, 67, 68, 72, 76, 88, 89, 94-97, 110-112, 126, 180-182, 217, 269-271, 282-285, 296, 319, and 320 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonaventura et al, 1999 (Example 1). Bonaventura et al teach a coating that is an aqueous buffered paint comprising an enzyme at a concentration between 5-40%, wherein the coating forms a temporary film.

Claims 1-6, 8-10, 64, 67, 68, 72-75, 79, 80, 82, 83, 88, 89, 94-97, 103, 105, 109-112, 126-131, 180-182, 217, 252, 269-271, 282-285, 296, 312, 319, and 320 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al, 1999. Cheng et al teach a variety of coatings comprising organophosphorus acid anhydrolase (Table 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 81 and 251 are rejected under 35 U.S.C. 103(a) as being unpatentable over over Sau et al, 1999, Bonaventura et al, 1999, or Cheng et al, 1999 in view of Stoye et al, 1993 (IDS). The teachings of Sau et al, Bonaventura et al, and Cheng et al are described above. Neither Sau et al, Bonaventura et al, Cheng et al, nor any combination thereof teach multi-pack coatings wherein only one layer comprises the active biomolecule. Stoye et al teach organic cellulose ester coatings that are used as top coatings (pg 16-19; Fig 2.1). Such top coatings are included in multipack coatings. It would have been obvious to a person of ordinary skill in the art to include the active biomolecule of Sau et al, Bonaventura et al, or Cheng et al only in the top coating of the multipack coating. Motivation to do so derives from the desire to save money by including the biomolecule only in the top layer, where its activity would most efficiently process the appropriate environmental agent. The expectation of success is high, as top coatings and coatings containing active biomolecules are both known in the art. Therefore, Claims 81 and 251 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sau et al, 1999, Bonaventura et al, 1999, or Cheng et al, 1999 in view of Stoye et al, 1993.

Claims 275-278 and 289-292 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sau et al, 1999, Bonaventura et al, 1999, or Cheng et al, 1999 in view of Ausubel, 1997. The teachings of Sau et al, Bonaventura et al, and Cheng et al are described above. Neither Sau

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et al, Bonaventura et al, Cheng et al, nor any combination thereof teach coatings containing cellular particulate matter comprising an active biomolecule. Methods to make vectors comprising coding sequence for protein biomolecules and transforming the vector into microorganisms or mammalian cells in order to produce the encoded protein biomolecule are well known in the art (Ausubel et al). It would have been obvious to a person of ordinary skill in the art to use the methods of Ausubel et al to produce the enzymes of Sau et al, Bonaventura et al, or Cheng et al in microorganisms or mammalian cells, isolate a cellular lysate from cells, and use said lysate, containing the active biomolecule, in a coating. Motivation to do so derives from the ease in which active biomolecules can be produced and the cellular lysate used. The expectation of success is high, as vectors encoding protein biomolecules, transformed into a host cell, and used to make the encoded protein are common in the art. Therefore, Claims 275-278 and 289-292 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sau et al, 1999, Bonaventura et al, 1999, or Cheng et al, 1999 in view of Ausubel, 1997.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
Art Unit 1656



SHERIDAN SWOPE, Ph.D.
PATENT EXAMINER

SOURCES: Data were collected from a survey of 1,000 U.S. adults conducted by the Pew Research Center, March 10-14, 2010. The survey was conducted by telephone using a random-digit-dialing method. The margin of error for the entire survey is plus or minus 3.4 percentage points.

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ESTIMATED 2001 NORTH AMERICAN COATINGS

ESTIMATED 2001 NORTH AMERICAN COATINGS SALES: \$1.5 billion

Coatings are the most widely used industrial products in the world, and are found in virtually every aspect of modern life. They are used to protect and enhance the appearance of buildings, bridges, ships, automobiles, and other structures. Coatings are also used in a wide variety of other applications, including paints, inks, and adhesives.

The coatings industry is a highly competitive market, with many companies vying for market share. The industry is also highly regulated, with many government agencies involved in the process of approving new coatings products.

PARENT COMPANY: BASF AG

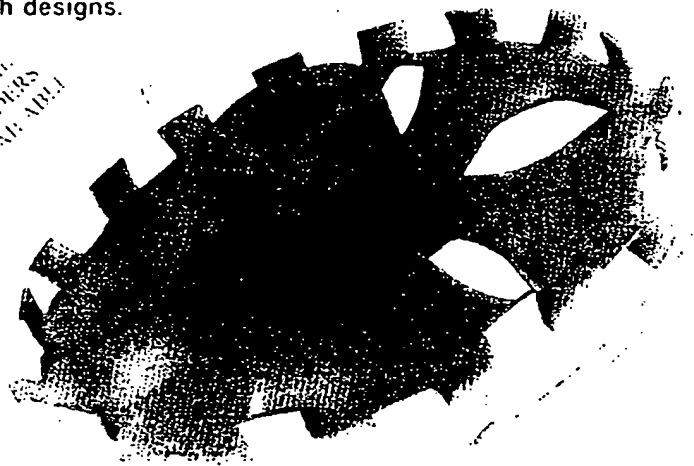
SOURCES: BASF AG, BASF Coatings Division

30. UNITED COATINGS
 10000 4th St.
 • 1999: \$74.4M
 1998: 10000 4th St., St. Louis, MO 63114
CEO/PRESIDENT: Peter J. Schmitt
ESTIMATED 2001 NORTH AMERICAN COATINGS SALES: \$100M
 United Coatings is a leading manufacturer of a wide range of specialty coatings for the construction, industrial and infrastructure markets and holds a number of patents for its 40+ employees and their team. Having moved to St. Louis in 1998, United Coatings is now a part of the global organization.

SOURCES: *Chemical Week*, 1/2001

[illegible]

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